Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of total extracts of Lactuca sativa seeds and Melissa officinalis leaves on dental anxiety of patients referring for dental extraction; A Randomized Double-blind clinical trial

Protocol summary

Study aim

Investigating the effectiveness of total extracts of lactuca sativa seed (LSS) and Melissa officinalis leaves (MOL) on dental anxiety, heart rate and blood oxygen saturation percentage of patients

Design

A clinical trial with a control group, double-blind, randomized by block randomization method, with a sample size of 48 patients, Split-mouth study

Settings and conduct

48 patients referred to the surgical department of the Faculty of Dentistry of Isfahan University of Medical Sciences are selected by considering the inclusion and exclusion criteria. After obtaining the patient's informed consent and demographic information, the Modified Dental Anxiety Scale for Dental Extraction Procedure (MDAS-DEP) is completed by the patient. The patient's heart rate and oxygen saturation percentage are measured using a pulse oximeter and recorded in the patient's initial questionnaire. Half an hour before the start of treatment, a capsule containing plant extract or placebo is given to the patient along with a glass of water. After the tooth extraction, the anxiety questionnaire is completed by the patient again, and the patient's heart rate and oxygen saturation percentage are measured again and recorded in the patient's secondary questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients over 18 years of age, referred for extraction of non-impacted bilateral molar or premolar teeth. Non-inclusion criteria: pregnancy, lactation and using anxiolytic drugs and etc.

Intervention groups

Half an hour before the start of treatment, one capsule containing 100 mg of total extract of LSS or one capsule containing 100 mg of total extract of MOL or one capsule containing 100 mg of corn starch as a placebo, depending on the study group, is given to the patient along with a glass of water.

Main outcome variables

Anxiety score, heart rate, blood oxygen saturation percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221127056634N2**
Registration date: **2024-10-31, 1403/08/10**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-31, 1403/08/10**
Update count: **0**

Registration date

2024-10-31, 1403/08/10

Registrant information

Name

Ali Mazdak

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-31, 1403/08/10

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of total extracts of Lactuca sativa seeds and Melissa officinalis leaves on dental anxiety of patients referring for dental extraction; A Randomized Double-blind clinical trial

Public title
Investigating the effect of total extracts of Lactuca sativa seeds and Melissa officinalis leaves on dental anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years old Patients referred for bilateral extraction of two molar or premolar teeth Having a healthy mental state and the ability and informed consent to complete the questionnaire
Exclusion criteria:
Taking CNS depressant and anxiolytic drugs such as benzodiazepines in the past fifteen days Pregnancy or lactation Continuous consumption of Sanabel Noma syrup or other lettuce seed products during the past month Continuous consumption of Nejabal capsule or other Melissa officinalis products during the last month History of allergy to lettuce or its seeds or Melissa officinalis
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **48**
More than 1 sample in each individual
Number of samples in each individual: **2**
After extraction of one tooth, drug treatment is received and after extraction of the opposite tooth in the following week, placebo treatment is received or vice versa.
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients is done in two stages. In the first stage, patients are randomly assigned to one of the two treatment arms (lettuce seed or Melissa officinalis leave), and then in the second stage, two parts of each patient's mouth will be randomly assigned to drug and placebo treatment in each of the two treatment groups. Block randomization method is used with the aim of achieving groups of equal size in the first stage. The number of required blocks according to the total number of the estimated sample (48 patients) is 8 blocks, and the size of each block varies between 4,6 and 8. (2 blocks of 6, 3 blocks of 4 and 3 blocks of 8). In each block, according to the size specified for it, considering two treatment groups A (lettuce seeds), B (Melissa officinalis leaves), first all possible conditions are determined for the order of treatment allocation. For example, for blocks of size 4, the set of possible states for the order of allocation of the two desired treatments is considered including six orders AABB, ABAB, ABBA, BABA, BBAA and ABBA. Then by choosing one of the arrangements randomly from the set of all possible arrangements, the patients are allocated to two treatments A and B respectively. This pattern is repeated for other consecutive blocks as well until all the sample are randomly assigned to treatment groups. In the second stage, within each treatment group, the left and right parts of each patient's mouth (considering only one tooth in each part) were randomly selected by tossing a coin to one of the two treatment orders of the right tooth - drug treatment, left tooth - placebo (if the appearance heads) or left tooth - drug treatment, right tooth - placebo (if tails appears) are allocated.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to blindness and not inform the patient about the received treatment, the capsules will have the same size and appearance, and the patient will not know the type of substance inside. Also, the statistician who analyzes the results will not know about the study groups of the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Schools of Pharmacy and Nutrition, Isfahan University of Medical Scien
Street address
School of Pharmacy, Isfahan University of Medical Sciences, Hezar jerib st.
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81746-73461
Approval date
2024-04-14, 1403/01/26
Ethics committee reference number

IR.MUI.PHANUT.REC.1403.008

Health conditions studied

1

Description of health condition studied
Dental anxiety
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety score in the questionnaire
Timepoint
Half an hour before the intervention (taking medicine), After the tooth extraction procedure
Method of measurement
Modified Dental Anxiety Scale for Dental Extraction Procedure questionnaire

2

Description
Heart rate
Timepoint
Half an hour before the intervention (taking medicine), After the tooth extraction procedure
Method of measurement
Pulse oximeter device

3

Description
Blood oxygen saturation percentage
Timepoint
Half an hour before the intervention (taking medicine), After the tooth extraction procedure
Method of measurement
Pulse oximeter device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: Lettuce seed-placebo group: In one session, the patient receives a capsule containing 100 mg of spray-dried total extract powder of Lactuca Sativa seeds (obtained from Marwarid Gharb Khorasan Pharmaceutical Company). In the next session, when the patient comes to have his/her opposite tooth extracted, he/she receives a capsule containing 100 mg of corn starch as placebo. (or vice versa depending on randomization)
Category
Treatment - Drugs

2

Description
Intervention group B: Melissa officinalis leaves-placebo group: In one session, the patient receives a capsule containing 100 mg of spray-dried total extract powder of Melissa officinalis leaves (obtained from Marwarid Gharb Khorasan Pharmaceutical Company). In the next session, when the patient comes to have his/her opposite tooth extracted, he/she receives a capsule containing 100 mg of corn starch as placebo. (or vice versa depending on randomization)
Category
Treatment - Drugs

3

Description
Control group: As explained, each patient is placed in one session in the intervention group and one session in the control group. (split-mouth design)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry of Isfahan University of Medical Sciences
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number
2402324

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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Position
Dentist-Researcher at the Pharmaceutical Sciences Research Center

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable